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August 8, 2016

Document Processing Desk (DCI/AD)
Antimicrobials Division (7510P)
Office of Pesticide Programs
Environmental Protection Agency
One Potomac Yard (South Building)
2777 S. Crystal Drive
Arlington, VA 22202

Attention: Reevaluation Team Leader, PM#36

re: GDCI-083301-1554
Case #3074
Hexahydro-1,3,5-tris(2-hydroxyethyl)-s-triazine (HHT)
Response to Data Call-In
Registrant: Surety Laboratories (Company No. 68868)

Dear Sir or Madam:

On behalf of Surety Laboratories, I am submitting the following documents in response to the Generic Data Call-In (GDCI) notice for Hexahydro-1,3,5-tris(2-hydroxyethyl)-s-triazine (HHT) that was issued in May, 2016.

- Data Call-In Response Form.
- Requirements Status and Registrant's Response Form and Attachments.

Since there are a some key outstanding issues that involve the GDCI, Surety is requesting that a meeting be scheduled as soon as possible so that these issues can be resolved. A request for a meeting was previously submitted to the Agency (see attachment).

If you have any questions regarding this response, please contact me at (202) 393-3903, ext. 114 or by e-mail at eharrison@lewisharrison.com.

Sincerely,

Eliot Harrison
Agent for Surety Laboratories

United States Environmental Protection Agency
Washington, D.C. 20460
DATA CALL-IN RESPONSE

OMB Approval 2070-0174
EPA FORM 6300-4

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.
Use additional sheet(s) if necessary.

1. Company Name and Address	2. Case # and Name	3. Date and Type of DCI and Number
SURETY LABORATORIES 2 STEWART COURT DENVILLE, NJ 07834	3074 - Hexahydro-1,3,5-tris(2-hydroxyethyl)-s-triazine Chemical # and Name: 083301 Hexahydro-1,3,5-tris(2-hydroxyethyl)-s-triazine	06-May-2016 GENERIC ID # GDCI-083301-1554

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data Requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is an MUP and I agree to satisfy the MUP requirement on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirement on the attached form entitled "Requirements Status and Registrant's Response."
68868-1			✓	N/A	N/A

8. Certification: I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative Eliot Harrison, Agent for Surety

9. Date 8-8-2016

10. Name of Company SURETY LABORATORIES

11. Phone Number 202 393-3903

United States Environmental Protection Agency
Washington, D.C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

OMB Approval 2070-0174
EPA FORM 6300-3

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

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SURETY LABORATORIES 2 STEWART COURT DENVILLE, NJ 07834	3074 - Hexahydro-1,3,5-tris(2-hydroxyethyl)-s-triazine Chemical # and Name: 083301 Hexahydro-1,3,5-tris(2-hydroxyethyl)-s-triazine	06-May-2016 GENERIC ID # GDCI-083301-1554

4. Guideline Requirement Number	5. Study Title		PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
	Nontarget Plant Protection Data Requirements (Conventional Chemical)									
850.4400	Aquatic Plant Toxicity Using Lemna spp	(8)	N				X,Y,Z	TGAI	12	9
	Terrestrial and Aquatic Nontarget Organisms Data Requirements (Conventional Chemical)									
850.1300	Daphnid chronic toxicity test	(8)	N				X,Y,Z	TGAI	12	9
850.1400	Fish early-life stage toxicity test	(8)	N				X,Y,Z	TGAI	12	9
	Toxicology Data Requirements (Conventional Chemical)									
870.6200	Neurotoxicity screening battery	(6, 8, 14)	Y				X,Y,Z	TGAI	12	9
870.7485	Metabolism and pharmacokinetics	(8)	N				X,Y,Z	PAIRA	24	9
870.7800	Immunotoxicity	(8)	N				X,Y,Z	TGAI	12	9

10. Certification: I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknow ledge that any know ingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative Eliot Harrison, Agent for Surety

11. Date 8-8-2016

12. Name of Company SURETY LABORATORIES

13. Phone Number 202 393-3903

ACT 114

United States Environmental Protection Agency
Washington, D.C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

OMB Approval 2070-0174
EPA FORM 6300-3

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4. Guideline Requirement Number	5. Study Title		PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
835.1110	Activated sludge sorption isotherm	**(5, 8, 11)**	N				X,Y,Z	COMMENT	12	9
835.1230	Sediment and soil absorption/desorption for parent and degradates	**(5, 8)**	N				X,Y,Z	COMMENT	12	9
835.2120	Hydrolysis of parent and degradates as a function of pH at 25 C	**(5, 8)**	N				X,Y,Z	COMMENT	12	2
835.3110	Ready biodegradability	**(1, 5, 8)**	N				X,Y,Z	COMMENT	12	9
835.3220	Porous pot test	**(1, 5, 8)**	N				X,Y,Z	COMMENT	12	9
835.3240	Simulation Test-Aerobic Sew age Treatment-Activated Sludge	**(1, 5, 8)**	N				X,Y,Z	COMMENT	12	9
835.3280	Simulation Tests to Assess the Biodegradability of Chemicals	**(1, 5, 8)**	N				X,Y,Z	COMMENT	12	9
835.4300	Aerobic aquatic metabolism	**(5, 8)**	N				X,Y,Z	COMMENT	24	9
850.3300	Modified Activated Sludge, Respiration Inhibition Test	**(5, 8, 10)**	N				X,Y,Z	COMMENT	12	9

Emily Agent for Surety

8-9-2016

United States Environmental Protection Agency
Washington, D.C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

OMB Approval 2070-0174
EPA FORM 6300-3

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1. Company Name and Address	2. Case # and Name	3. Date and Type of DCI and Number
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4. Guideline Requirement Number	5. Study Title		PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
850.4500	Algal Toxicity	(7, 8)	N				X,Y,Z	TGAI	12	9
850.4550	Cyanobacteria (Anabaena flos-aquae) Toxicity	(7, 8)	N				X,Y,Z	TGAI	12	9
875.1200	Dermal exposure--Indoor	(8, 12, 14)	Y				X,Y,Z	TEP	24	9
875.1400	Inhalation exposure--indoor	(2, 8, 12, 14)	Y				X,Y,Z	COMMENT	24	1
875.1700	Product Use Information	(8)	N				X,Y,Z	TEP	12	1
875.2400	Dermal exposure	(3, 8, 14)	Y				X,Y,Z	TEP	24	9
875.2500	Inhalation exposure	(2, 8, 9, 14)	Y				X,Y,Z	COMMENT	24	1
SS-1218	Nature of Residue on Surfaces	(4, 8, 14)	Y				X,Y,Z	TGAI	24	1
SS-Migration	Migration studies	(4, 8, 13, 14)	Y				X,Y,Z	TEP	12	1

Agent for Surety

8-8-2016

ATTACHMENT TO REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORM

Registrant: Surety Laboratories (Company No. 68868)
Active Ingredient: Hexahydro-1,3,5-tris(2-hydroxyethyl)-s-triazine

Surety Laboratories is requesting that the Agency waive several of the studies listed in the Generic Data Call-In (GDCI) for hexahydro-1,3,5-tris(2-hydroxyethyl)-s-triazine (HHT). The specific data requirements that waivers are being requested for are discussed below. In addition, comments are being provided regarding some of the data requirements for which studies will be submitted.

Environmental Fate and Non-Target Organism Data Requirements

Data waivers are being requested for the following studies:

Guideline Number	Study Title
835.1110	Activated sludge sorption isotherm
835.1230	Sediment and soil absorption/desorption for parent and degradates
835.2120	Hydrolysis of parent and degradates as a function of pH at 25°C
835.3110	Ready biodegradability
835.3220	Porous pot test
835.3240	Simulation test- Aerobic sewage treatment – activated sludge
835.3280	Simulation tests to assess the biodegradability of chemicals
835.4300	Aerobic aquatic metabolism
850.3300	Modified activated sludge, Respiration inhibition test
850.4400	Aquatic plant toxicity using Lemna
850.1300	Daphnid chronic toxicity test
850.1400	Fish early life-stage toxicity test

Basis for Waivers

As discussed in the submission provided to the Agency on July 11, 2016 (attached), HHT is expected to rapidly degrade upon aqueous dilution. The predominant degradates are monoethanolamine and formaldehyde. The substance 1,3,5-trimethyl triazine does not result from the degradation of HHT. Accordingly, the substances present in the environment from the use of HHT will be monoethanolamine and formaldehyde (minor degradates, methanol and 1,3-oxazolidine, might also be present). Therefore, the requested environmental fate and ecotoxicity studies would be actually be testing a mixture of monoethanolamine and formaldehyde, not HHT or 1,3,5-trimethyl triazine. Since there is an ample environmental fate and ecological effects database on monoethanolamine and formaldehyde, conducting additional studies with this mixture will not provide any useful additional data.

The degradation behavior of HHT was evaluated in the hydrolysis study with metal working fluids that was previously submitted to the Agency (MRID No. 48741001) and the study recently submitted by Troy Chemical Company ("HHT Hydrolysis –Evidence on Dissociation"). If there are any issues that remain regarding the degradation of HHT and the resulting degradates, these can be addressed in a follow-up hydrolysis study. In this case, the Agency should reserve the GDCI environmental fate studies until a final determination is made regarding the degradation behavior of HHT.

Toxicology Data Requirements

Data waivers are being required for the following studies:

Guideline Number	Study Title
870.6200	Neurotoxicity Screening Battery
870.3485	Metabolism and Pharmacokinetics
870.7800	Immunotoxicity

Basis for Waiver Request

In 2010, HHT registrants met with the Agency to discuss the toxicology data requirements that were part of the Reregistration Data Call-In for HHT. At that time, the Agency agreed that the toxicity of formaldehyde donor products, such as HHT, are directly linked to formaldehyde and agreed that the toxicological data requirements for HHT should be held in abeyance until the Science Advisory Panel (SAP) evaluated the updated IRIS document on formaldehyde. The same agreement should be applied to the above toxicology studies.

As with the environmental fate and non-target organisms data requirements discussed above, if the Agency accepts the degradation pathway for HHT as outlined in the submission of July 11 2016, toxicology studies using HHT will essentially be a test of a monoethanolamine + formaldehyde mixture. There is a large toxicology data base on both of these substances so the requested toxicology studies are unlikely to provide any additional useful information. If the degradation data provided on HHT is not sufficient for the Agency to make a determination on the testing requirements for this substance, a bridging study or a comparison of the HHT database with formaldehyde and monoethanolamine should be considered.

Exposure Data Requirements

Surety is requesting that the Agency hold the dermal exposure data requirements, as noted below, in abeyance until a determination is made regarding the substances that are associated with dermal exposure from the use of HHT. Surety has previously provided an inhalation study for the detergent use of HHT and will provide a similar study for cleaning products, if necessary.

Guideline Number	Study Title
870.1200	Dermal Exposure Indoor
870.2400	Dermal Exposure- Post Application

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July 11, 2016

Stephen Savage
Chemical Review Manager
Antimicrobials Division (7510P)
Office of Pesticide Programs
Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

re: Hexahydro-1,3,5-tris (2-hydroxymethyl)-s-triazine (HHT)
Generic Data Call-In (GDCI) No. 083301-1554
Request for Meeting

Dear Mr. Savage:

On behalf of several registrants (Lonza Inc. Buckman Laboratories, Troy Chemical Company, Stepan Company and Surety Laboratories) that are subject to the GDCI for HHT, I am requesting that a meeting be scheduled to discuss the GDCI.

Subsequent to the issuance of the Final Work Plan for HHT and the GDCI, Troy Chemical Company received the results of a detailed and comprehensive chemistry study that evaluated the hydrolysis/degradation of HHT. The results of this work call into question the hydrolysis pathway for HHT that was postulated in the Final Work Plan (FWP) for this substance. On page 10 of the FWP, the Agency assumed that formaldehyde is released from HHT by cleaving carbon-carbon (C-C) bonds. If HHT is degraded in this manner, the degradates will be formaldehyde and 1,3,5-trimethyl triazine. The data collected in the Troy sponsored study clearly demonstrate that cleavage occurs among the carbon-nitrogen bonds. This pathway cleaves the triazine ring and results in formaldehyde and monoethanolamine (MEA). Another key finding is that dilute solutions of HHT are rapidly degraded. Accordingly, any environmental fate, toxicity or exposure studies performed with dilute solutions of HHT will actually be testing a mixture of formaldehyde and MEA. Since there is a substantial safety data base for both formaldehyde and MEA any further testing on HHT will not provide any additional or useful information.

A summary of the hydrolysis/degradation study mentioned above is attached. A complete copy of the study will be submitted through front-end processing. Please note that the study was conducted using nuclear magnetic resonance (NMR). Previous chemistry studies showed that methods specific for formaldehyde (e.g. dinitrophenyl hydrazine derivatization) or high-performance liquid chromatograph (HPLC) are not suitable for the detection of HHT since they destroy the products equilibrium with formaldehyde, resulting in an inaccurate assessment of HHT and its degradates. NMR was chosen due to its non-destructive nature and its ability to capture the true behavior of HHT and formaldehyde.

An agenda for the meeting is also attached.

Sincerely,

Eliot Harrison,
On behalf of Troy Chemical, Lonza Inc,
Stepan Company, Buckman Laboratories,
Surety Laboratories

Agenda for Meeting Between Registrants of Hexahydro-1,3,5-tris (2-hydroxymethyl)-s-triazine (HHT) and Antimicrobials Division Regarding the GDCI for HHT

Date/Time: To be determined
Participants: Buckman Laboratories, Lonza Inc., Troy Chemical Company, Stepan Company and Surety Laboratories

Agenda

1. Recent chemistry studies on HHT
   - Description of the studies
   - Results of the studies

2. Implication of the Chemistry Studies for HHT Testing and Assessments
   - GDCI studies based on pathway outlined in Final Work Plan (FWP)
   - Chemistry studies do not support this pathway
   - Need for conducting GDCI studies if alternative pathway is correct

3. Responding to GDCI
   - Submission of complete chemistry study
   - Waiver requests
   - Amend FWP and reissue GDCI?